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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/697,793 | 10/30/2003 | Michael E. Landry | 5259-10705 | 1158 |

23492 7590 10/11/2006

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| EXAMINER |
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SWIGER III, JAMES L

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| ART UNIT | PAPER NUMBER |
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3733

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

111

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|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/697,793 | LANDRY ET AL. | |
| | Examiner | Art Unit | |
| | James L. Swiger | 3733 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 123-150 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 123-150 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/30/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/7/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 123-124, 126-128, 131, 134-136 and 149 are rejected under 35

U.S.C. 102(b) as being anticipated by Michelson (US Patent 5,015,247). Michelson discloses a method of implanting a spinal stabilization system including the steps of inserting a bone fastener assembly into a vertebral body (see Fig. 4) which would have to be accessed via an incision in the skin, inserting or disposing a sleeve between the incision and the fastener (Col. 9, lines 20-37), inserting an elongate member (24) into the sleeve (see Fig. 3), and securing elongate member (104) to the bone fastener assembly (50). Michelson also discloses the step of advancing a bone fastener through to the target location (Col. 7, lines 1-5) and where it is considered to be inserted longitudinally and angled relatively upon insertion and extends at least outwardly from the sleeve (See Col. 9, lines 35-45). The device also includes a sleeve wall, a positioning tool (100), and at least two target tools for positioning (see Fig. 4), wherein the elongate member may secure both.

Claims 123-124, 126-128, 134, 148-150 rejected under 35 U.S.C. 102(e) as being anticipated by Davison (US Patent 6,530,926). Davison discloses a method of stabilizing vertebrae comprising the steps of anchoring a bone fastener that is inserted into the body of a patient, as it is disposed in a sleeve having a sleeve wall to the target site (Col. 15, lines 7-15). An elongate member (21) may be inserted into passage substantially in at least a first orientation (10) to help guide the fastener assembly for securing. A portion of the elongate member may extend outwardly (see Fig. 5). The working space may also be dilated (110). Davison also discloses that a second sleeve, or as a cannula into a patient for securing a fastener or fixation device (Col. 16, lines 5-10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 125, 129-132, and 135-136 rejected under 35 U.S.C. 103(a) as being unpatentable over Davison '926 in view of Lutz (US Patent 6,183,472). Davison discloses the claimed method except for the steps having a sleeve that is detachably coupled, or a bone fastener that has a slot to receive an elongate member, or that has two arms extending therefrom, or a step that comprising grasping the elongate member with a positioning tool, or wherein the elongate member may specifically with its second end secure to the bone fastener. Lutz discloses a sleeve that is detachably coupled

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(64/66, col. 3, lines 28-43), a bone fastener that has a slot to receive an elongate member (34), and two arms extending for grasping the elongate member (approx. 26/28), a step that includes grasping of the fastener with the elongate member (see col. 4, lines 40-57). The end portion (70) may be used to adjust the sleeve portion (60/62) and where the detachably coupled ends (60/62) can then move and articulate the bone fastener (Fig. 5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Davison having at least a sleeve that is detachably coupled, or a bone fastener that has a slot to receive an elongate member, or that has two arms extending therefrom, or a step that comprising grasping the elongate member with a positioning tool, or wherein the elongate member may specifically with its second end secure to the bone fastener in view of Lutz to better use the device for the fixation of vertebrae.

Claims 139-142, and 144-145 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Davison '926 and Lutz '472 as applied to claim 136 above, and further in view of Justis et al. (US Patent 6,530,929). The combination of Davison '926 and Lutz '472 disclose the claimed method except for the step of detachably coupling a second sleeve, or having a first and second sleeve facing one another, and wherein the proximal ends of the first and second sleeves are coupled. Justis et al. disclose a device having two sleeves attached at their proximal ends (26a and 26b) and wherein two sleeves are detachably coupled to respective bone anchors (See fig. 4, and Col. 7, lines 25-30), enabling the anchors to be positioned relative to one another. The sleeves may face one another (see Fig.1, and at least 70a faces the

opposing side of 70b). The distance between the first and second sleeve may be estimated by the user; likewise the length of the elongate member may be selected appropriate to use by at least an anchor extension (30a). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the method of the combination of Davison '926 and Lutz '472 having at least the above steps as provided by Justis et al. *supra* to better use the device in securing vertebrae.

Claims 137-138 are rejected under 35 U.S.C. 103(a) as being unpatentable over combination of Davison '926 and Lutz '472 as applied to claim 136 above, and further in view of Gerber et al. (US Patent 6,360,750). The combination of Davison '926 and Lutz '472 disclose the claimed method except for the step of forming a dilated tissue plane and moving the tissue. Gerber et al. teaches the use of a dilating device for moving tissue (Col. 5, lines 40-55). It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of the combination of Davison '926 and Lutz '472 including at least the step of dilating tissue in view of Gerber et al. to better access the vertebrae in the spine.

Claim 133 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davison '926 in view of Branch et al. (US Patent 6,200,322). Davison disclose the claimed method except for a sleeve having a channel that is along a majority of the length of the sleeve. Branch et al. disclose a sleeve that has a channel extending a length of the sleeve (see Fig. 4b) that allows for better spinal access to the spine for implanting a fixation element (Col. 3, lines 15-25 and 37-43). It would have been obvious to one having ordinary skill in the art at the time the invention was made to

perform the method of Davison having at least a sleeve that is along a majority of the length of the curve in view of Branch et al. to better access the spine.

Claim 143 is rejected under 35 U.S.C. 103(a) as being unpatentable over combination of Davison '926 and Lutz '472 and Justis et al. '750 as applied to claim 142 above, and further in view of Branch et al. '322. The combination of Davison '926 and Lutz '472 and Justis et al. '750 disclose the claimed method except for a channel extending substantially the entire length. Branch et al. disclose a sleeve that has a channel extending a length of the sleeve (see Fig. 4b) that allows for better spinal access to the spine for implanting a fixation element (Col. 3, lines 15-25 and 37-43). It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of the combination of Davison '926 and Lutz '472 and Justis et al. '750 having at least a sleeve channel extending substantially the entire length in view of Branch et al. to better access the spine.

Claims 146-147 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davison '926 in view of Lutz '472. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of Davison in view of Lutz having a third anchor assembly, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

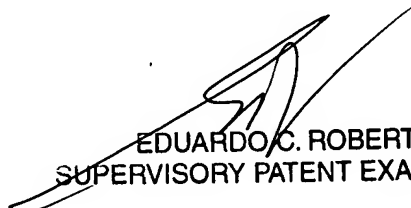
Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS 9/29/2006

JLS


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER